

U.S. Application No. 10/740,208
October 14, 2008
Response to Notice of Allowance dated July 16, 2008

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

Claim 1. (Previously Presented) A modified release pharmaceutical composition in the form of a capsule, the capsule comprising:

- a capsule body
- a coated or uncoated capsule cap,
- at least one tablet and
- a granulate

wherein the capsule body and cap are assembled so as to encapsulate at least the tablet and granulate together with trapped gas and at least an exposed portion of the capsule body of the assembled capsule is coated with a coating which is substantially insoluble or poorly soluble in an acidic aqueous medium wherein the assembled capsule floats or at least remains buoyant in the acidic aqueous medium for at least about an hour.

Claim 2. (Previously Presented) The pharmaceutical composition according to claim 1 where the granulate comprises a pharmaceutically active substance.

Claim 3. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the tablet and the granulate comprise a pharmaceutically active substance.

Claim 4. (Previously Presented) The pharmaceutical composition according to claim 3 wherein the pharmaceutically active substance is selected from the pharmaceutically active substances having an absorption window in the upper part of the gastrointestinal tract.

Claim 5. (Currently Amended) The pharmaceutical composition according to claim 4 wherein the active substance is selected from the group consisting of antihypertensives, peptidomimetic substances, antiulcer agents, analgesics, antipsychotics, antidepressants, antiepileptics, cytostatics, antimigraine agents, antiviral substances, antibiotics, anti-inflammatory

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agents, sedatives, antidiabetic agents, antihistamines, vitamins, bronchodilators, diuretics, hypolipemic agents, antiobesity agents, and combinations of one or more of thereof.

Claim 6. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule body and the cap comprise hydroxypropyl methylcellulose.

Claim 7. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule body is coated with a coating which is insoluble in an acidic medium.

Claim 8. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule cap is coated with a coating which is insoluble in an acidic medium.

Claim 9. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule body is coated with a coating which is insoluble independent of pH.

Claim 10. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule cap is coated with a coating which is insoluble independent of pH.

Claim 11. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule body is coated with a coating which is poorly soluble in an acidic medium.

Claim 12. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule cap is coated with a coating which is poorly soluble in an acidic medium.

Claim 13. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule body is coated with a coating which is poorly soluble independent of pH.

Claim 14. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule cap is coated with a coating which is poorly soluble independent of pH.

Claim 15. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule body is coated with a coating which is a combination of insoluble and soluble polymers.

Claim 16. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule cap is coated with a coating which is a combination of insoluble and soluble polymers.

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Claim 17. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule cap is coated with a coating which is better soluble than a coating of the capsule body.

Claim 18. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule body is coated with a coating which is better soluble than a coating of the capsule cap.

Claim 19. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule body and cap are coated with substantially the same coating and wherein the coating is sparingly soluble in acidic medium and the material comprising the capsule body and cap are more soluble than the coating.

Claims 20 – 21. (Cancelled)

Claim 22. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule body coating comprises copolymers of acrylic and methacrylic acid.

Claim 23. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule cap comprises copolymers of acrylic and methacrylic acid.

Claim 24. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule body coating comprises a combination of ethylcellulose and hydroxypropylmethylcellulose.

Claim 25. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule cap coating comprises a combination of ethylcellulose and hydroxypropylmethylcellulose.

Claim 26. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule body coating comprises a combination of ethylcellulose and hydroxypropylcellulose.

Claim 27. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule cap coating comprises a combination of ethylcellulose and hydroxypropylcellulose.

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Claim 28. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule body is coated and the capsule cap uncoated.

Claim 29. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the capsule cap is coated and the capsule body uncoated.

Claim 30. (Original) The pharmaceutical composition according to claim 1 wherein the granulate comprises at least one lipophilic or hydrophilic substance.

Claim 31. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the granulate comprises hydroxypropylmethylcellulose.

Claim 32. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the granulate optionally comprises a material selected from the group consisting of fillers, binders, disintegrants, glidants, lubricants, excipients, and combinations of one or more thereof.

Claim 33. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the composition of the tablet is substantially the same as the composition of the granulate.

Claim 34. (Original) The pharmaceutical composition according to claim 1 wherein the composition of the tablet is different from the composition of granulate.

Claim 35. (Original) The pharmaceutical composition according to claim 1 wherein the tablet comprises at least one lipophilic or hydrophilic substance.

Claim 36. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the tablet comprises hydroxypropylmethylcellulose.

Claim 37. (Previously Presented) The pharmaceutical composition according to claim 1 wherein the tablet optionally comprises a material selected from the group consisting of fillers, binders, disintegrants, glidants, lubricants, excipients, and combinations of one or more thereof.

Claim 38. (Original) The pharmaceutical composition according to claim 1 wherein the tablet does not contain an active substance.

Claim 39. (Previously Presented) The pharmaceutical composition according to claim 1 which comprises one, two or more tablets positioned in the capsule body so as to impede any flow of aqueous medium through a open end of the body into a closed end thereof containing the granulate

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upon dislodgment of the cap from the body and/or dissolution of at least part of the cap in contact with the aqueous medium.

Claim 40. (Previously Presented) The pharmaceutical composition according to claim 39 wherein the composition of all tablets is the same.

Claim 41. (Previously Presented) The pharmaceutical composition according to claim 39 wherein the composition of the tablets is different.

Claim 42. (Previously Presented) The pharmaceutical composition according to claim 39 wherein the tablets contain different active substances.

Claim 43. (Previously Presented) A capsule containing a pharmaceutical composition for release of contents into the upper gastrointestinal tract which comprises a capsule body assembled with a capsule cap to sealably encapsulate therein at least one tablet, granulate, and an amount of a gaseous material and to substantially isolate the tablet, granulate, and gaseous material from an environment surrounding the assembled capsule wherein at least the capsule body or the capsule cap of the assembled capsule is substantially insoluble in aqueous acidic medium with a remaining part of the capsule having at least a slow solubility in the aqueous acidic medium so that the assembled capsule floats adjacent the surface of the aqueous medium for at least about one hour for controlled release of material from inside the capsule into the medium while the capsule remains floating or at least buoyant in the medium.

Claim 44. (Previously Presented) The capsule of claim 43 wherein the capsule body in the assembled capsule includes a coating over at least its exposed outside surface of a material which is substantially insoluble in the aqueous acidic medium.

Claim 45. (Previously Presented) The capsule of claim 43 wherein the material is selected from the group consisting of copolymers of acrylic and methacrylic acid and a combination of ethylcellulose and hydroxypropylmethycellulose.

Claim 46. (Previously Presented) The capsule of claim 43 wherein the tablet or the granulate comprise an active pharmaceutical substance selected from the group consisting of antihypertensives, peptidomimetic substances, antiulcer agents, analgesics, antipsychotics, antidepressants,

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antiepileptics, cytostatics, antimigraine agents, antiviral substances, antibiotics, anti-inflammatory agents, sedatives, antidiabetic agents, antihistamines, vitamins, bronchodilators, diuretics, hypolipemic agents, antiobesity agents, and combinations of one or more of thereof.